REMARKS

The Office Action makes final the restriction requirement and therefore claims 1-8 and 21-30 are withdrawn from consideration and the appropriate labels are used above.

Claim 12 is been amended; claims 9-20 are currently pending; claims 1-8 and 21-30 are currently withdrawn from consideration.

The Patent Office objects to the specification as failing to provide proper antecedent basis for the temperature range of claims 18-20. For support, the Patent Office cites MPEP §608.01(o). However, §608.01(o) does not require each claimed parameter range to be specifically set forth in the specification. §608.01(o) is directed to structural claim terms, not ranges. Instead the long established rule is that a broad range set forth in the specification supports a narrower claimed range. Therefore the broader range of 40-85°C on page 8, line 26 of the specification provides adequate support for the narrower claim range limitations of claims (8-20). For example, *In re Wertheim*, 191 USPQ 90, 97-98 (CCPA 1976) makes it clear that a range of 25%-60% in an original specification meets the written description requirement for a narrower claim limitation of 35%-60% even though the claimed range was not specifically cited in the *Wertheim* specification. *See also In re Blaser*, 194 USPQ 122, 125 (CCPA 1977) and MPEP § 2163.05 III, which cites *In re Wertheim*. Thus, it has long been the practice in U.S. Patent law that a broad range set forth in the specification supports and provides antecedent basis for a narrower range in a claim. Accordingly, the objection to the specification is respectfully traversed.

Claim 12 is objected to due to some typographical errors. Claim 12 is also rejected under 35 U.S.C. § 112 second paragraph as being indefinite due to the typographical errors. In response, claim 12 has now been amended to make it clear that the first section of the stepped enclosure comprises a flared proximal end and the second section of the stepped enclosure comprises a flared distal end, which is consistent with the language of independent claim 9. The second section of the enclosure is the smaller section disposed over the stent while the proximal first section is the larger section disposed over the proximal portion of the balloon disposed upstream or proximately from the stent. In figure 4, the first section is indicated at

reference numeral 41 while the second section is indicated at reference numeral 42. See also page 7, lines 17-32 of the application as filed. Accordingly, applicants respectfully submit that the objections and §112 rejection of claim 12 have been traversed.

Turning to the rejections based upon the prior art, claims 9, 13 and 16-17 are rejected under 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 5,836,965 ("Jendersee"). In response, applicants present the following remarks directed primarily at independent claim 9.

In order for a reference to serve as an anticipating reference for a §102 rejection, the standards of MPEP §2131 must be satisfied. Under MPEP § 2131,

> [t]o anticipate a claim, the reference must teach every element of the claim. 'A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.'

Applicant respectfully submit that Jendersee fails to teach or suggest numerous limitation of independent claim 9 and therefore the anticipation rejection of independent claim 9 and dependent claims 13 and 16-17 are improper and must be withdrawn.

First, independent claim 9 recites that the stepped enclosure is be placed over the stent and balloon so that the first section is disposed over the proximal section of the balloon and the second section of the stepped enclosure is disposed over the stent. As noted above, figure 4 and page 7 of the present application and claim 9 all consistently recite that the first section has an inner diameter that is greater than the inner diameter of the second section. Thus, the larger first section of the enclosure is placed over the portion of the balloon disposed proximately to the stent. Consequently, the smaller second section of the enclosure is placed over the stent so the stent does not move or expand upon inflation of the balloon

In this way, the proximal section of the balloon is able to inflate up against the inner diameter of the first section of the stepped enclosure. As a result, the proximal section of the balloon (not covered by the stent) is inflated to a diameter that is larger than the stent, which

fits within the smaller second section of the stepped enclosure. This is clearly illustrated in figure 5 of the present application. Upon deflation and removal of the enclosure as illustrated in figures 6 and 7, the proximal section 23 of the balloon 16 remains slightly enlarged so that it serves as a protection for the stent 25 upon withdrawal or retraction in the proximal direction during a procedure. See page 8, line 28 to page 9, line 13 of the present application

In contrast, Jendersee does not teach or suggest this fabrication method. As shown in figure 3 of Jendersee, relied upon by the Patent Office in making its rejection, the distal and proximal sheaths 42 (only the distal sheath 42 is labeled in figure 3 of Jendersee, but column 6, lines 46-47 make it clear that separate sheaths 42 are disposed over both ends of the balloon catheter 30 and a proximal sheath is shown on an opposing end of the large central sheath 44 from the smaller distal sheath 42 shown in figure 3 at Jendersee). Thus, in contrast to claim 9, Jendersee teaches the use of *smaller* sheaths 42 on the proximal and distal ends of the balloon 50 and a larger sheath 44 over the stent 10. Thus, upon inflation of the Jendersee balloon 50, no protective balloon portion is formed proximal to the Jendersee stent 10.

Instead, Jendersee merely teaches encapsulation which acts to securely anchor the stent 10 to the balloon 36 and provide portions of the balloon that extend past the inner diameter of the stent, but not past the outer diameter of the stent as illustrated by the sectional views of figures 5-6 of Jendersee. The only protection proximal to the stent taught by Jendersee is the use of the retainers 54 shown in figures 7-8. However, neither set of retainers 54 has a larger outer diameter than the stent and, even in the embodiment shown in figure 8, with the retainer 54 disposed below the balloon 36, the portion of the balloon 36 extending around the retainer 54 is not greater than the outer diameter of the stent.

Thus, Jendersee does not teach or suggest the placing of a stepped enclosure over a stent and balloon whereby the stepped enclosure includes a first section having a first larger inner diameter and a second section having a second smaller inner diameter whereby the second smaller section is placed over the stent and the first larger section is placed over the proximal portion of the balloon that extends upstream from the proximal end of the stent before it is connected to the outer tubular shaft. Jendersee, in fact, teaches the opposite. Jendersee teaches the use of a larger tubular element over the stent and smaller tubular elements over the proximal

and distal portions of the balloon. Thus, Jendersee does not teach or suggest the making of a pillowed proximal portion of the balloon whereby the proximal portion has a larger uninflated outer diameter than the crimped stent. Nowhere in Jendersee does he teach or suggest the formation of a protective element for the stent from a proximal portion of the balloon or the portion of the balloon disposed proximately to the stent.

Therefore, the anticipation rejection of claim 9 is improper as it does not teach or suggest every element of claim 9. Consequently, the anticipation rejection of dependent claims 13 and 16-17 are also improper as well.

Still further regarding claim 13, applicants disagree with the Patent Office position that the three separate tubular elements shown at 44 and 42 of figure 3 of Jendersee teach or suggest a stepped tube. In contrast, figure 3 of Jendersee teaches three separate tubular elements. The tubular elements are clearly not connected as shown by the spacing in figure 3. Further, the sheaths or tubular elements 42, 44 as described in column 6 of Jendersee are indicated to be separate elements and the placing of the interior sheaths 42 and exterior sheath 44 are done separately. See Jendersee at column 6, lines 46-50. Thus, claim 13 is not anticipated by Jendersee for this additional reason.

Regarding claim 16 and 17 Jendersee cannot anticipate these claims Jendersee clearly fails to anticipate independent claim 9 from which dependent claims 16 and 17 depend.

Turning to the obviousness rejections, the Patent Office rejects claims, 10-11, 12, 14-15 and 18-20 under 35 U.S.C § 103 as being unpatentable over Jendersee alone or Jendersee in view of U.S. Patent No. 5,704,845 ("Miraki") U.S. Patent No. 5,147,302 ("Euteneuer"), or U.S. Patent No. 6,629,350 ("Motsenbocker"). However, each one of these obviousness rejections fails to meet the standards of MPEP §2142 as each rejections fails to establish a *prima facie* case of obviousness. Under §2142,

> [t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference

> or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

Similar to MPEP § 2131, MPEP § 2142 also requires the prior art reference or references when combined to teach or suggest *all the claim limitations*. As noted above, Jendersee fails to teach or suggest the use of a stepped enclosure with a first larger diameter that is placed over a proximal section of the balloon extending proximately from the stent toward the distal end of the outer shaft and with a second smaller diameter that is placed over the stent to keep the stent from expanding upon inflation of the balloon. Jendersee fails entirely to teach or suggest any type of enclosure that allows a proximal section of the balloon, disposed between the stent and the distal end of the outer tube, to expand to a diameter that is larger than the unexpanded outer diameter of the stent. Jendersee fails entirely to teach or suggest any method in creating a protective cone or pillow from the proximal section of the balloon that serves to protect the stent upon retraction of the assembly during a procedure.

Therefore, Jendersee fails to teach or suggest every claim element of independent claim 9 and therefore the obviousness rejection of dependent claims 18-20, all of which depend from allowable claim 9, is improper and should be withdrawn.

The Office Action also rejects claims 10-11 as being obvious in view of Jendersee in view of Miraki. However, Miraki is only cited for the proposition that it discloses the use of a protective sheath or sleeve after the stepped enclosure is removed. In other words, Miraki only teaches the use of a protective sheath for packaging purposes. Miraki teaches nothing about the formation of a protective element for the stent from a proximal section of the balloon. Therefore, Miraki cannot supplement the deficiencies of Jendersee and the obviousness rejection of claims 10-11 is improper and must be withdrawn.

The Office Action also rejects claim 12 as being obvious in view of Jendersee in view of Euteneuer. However, Euteneuer is merely cited for the proposition that it discloses a protective sleeve or sleeves 50, 60 that are placed over the balloon during sterilization. Euteneuer does not teach or suggest a stent/balloon combination for the use of any portion of the balloon to serve as the protective element for a stent. Thus, Euteneuer cannot serve as a secondary reference to supplement the deficiencies of Jendersee, which also fails to teach or suggest the use of the proximal section of a balloon as a protective element for a stent. Therefore, the obviousness rejection in claim 12 is improper and should be withdrawn.

Finally, the Office Action rejects claim 14-15 as being obvious in view of Jendersee in view of Motsenbocker. However, Motsenbocker only teaches a crimping element. Motsenbocker teaches nothing about the stepped enclosure recited in independent claim 9 which Jendersee fails to completely teach or suggest. Motsenbocker teaches nothing about using a proximal section of a balloon as a protective element for a stent. Neither does Jendersee. Accordingly, the obviousness rejection of claims 14-15 based upon the Jendersee/Motsenbocker combination is improper and must be withdrawn.

Applicants respectfully submit that all rejections have been traversed in an early action indicating the allowability of claims 9-20 has earnestly solicited. If the examiner has any questions or comments regarding this amendment, he is invited to telephone the undersigned at the number listed below.

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Respectfully submitted,

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